DETAILED ACTION

Application Status

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 13, 2009 has been entered.

2. Claims 1-13 and 17-20 are pending and are under examination.

Claim Objection

3. Claim 1 is objected to because of the following informalities:

For clarity and precision of claim language it is suggested that claim 1 is amended to read:

"A method of treating an inflammatory disorder in a patient, the method comprising administering to said patient a pharmaceutical composition comprising a pharmaceutically acceptable carrier, wherein said composition comprises heme oxygenase-1 (HO-1), bilirubin, biliverdin, ferritin, iron, desoferoxamine, salicylaldehyde isonicotinoyl hydrazone, iron dextran, or apoferritin, in an amount sufficient to treat the inflammatory disorder, and wherein the inflammatory disorder is localized in the gastrointestinal tract".

Correction is required.

Claim Rejections - 35 USC ∋ 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-13 and 17-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a method of treating inflammatory disorder in a patient selected from the group consisting of inducing ferritin in the patient, expressing ferritin in the patient and administering a pharmaceutical composition. The recited method is not adequately described with respect to 'expressing a ferritin in the patient' as said method encompasses gene transfer, gene therapy or genetic engineering and the claims are not limited to any specific organism, thus encompasses a human. The instant specification at paragraph [0101] discloses that, "… it is contemplated that biliverdin reductase can be induced, expressed, and/or administered to a patient in situations where it is deemed desirable to increase bilirubin levels in the patient. The biliverdin reductase protein can be delivered to a patient, for example, in liposomes. Further, the present invention contemplates that increased levels of biliverdin

reductase can be generated in a patient via gene transfer. An appropriate gene therapy vector (e.g., plasmid, adenovirus, adeno-associated virus (AAV), lentivirus, or any of the other gene therapy vectors mentioned herein) that encodes biliverdin reductase, with the coding sequence operably linked to an appropriate expression control sequence, would be administered to the patient orally, via inhalation, or by injection at a location appropriate for treatment of a condition described herein". The description provided in the instant specification is exemplary, however, not limiting. No specific method is provided for example an *ex vivo* or *in vivo* process demonstrating the desired effects, and the art recognizes that gene therapy methodologies have pros and cons and might not produce the results desired. The specification and claims do not exclude humans, therefore, humans are contemplated, however only literal support is provided in the instant specification. No guidance is provided with said method practiced in a human subject with the desired effects. Thus, the specification lacks adequate written description to demonstrate to a skilled artisan that applicant was in possession of the claimed invention.

5. Claims 1-13 and 17-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating inflammatory disorders by for example, administering a composition comprising ferritin, does not reasonably provide enablement for a method of expressing ferritin in any organism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is

sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands, 858 F.2d at 737, 8 USPQ2d at1404 (Fed. Cir. 1988)*. The factors most relevant to the instant invention are discussed below.

The amount of experimentation required to practice the claimed invention is undue as the claims encompass the expression of ferritin in any organism via gene therapy, gene transfer or genetic engineering methods and said method is not exemplified in the instant specification. The art recognizes gene therapy as unpredictable based on the fact that this therapy is aimed at treating or eliminating the causes of diseases whereas other treatment modalities treat symptoms. The instant specification does not provide a method with for example gene transfer of somatic or germ-line cells that can take place either with an *ex vivo* or *in vivo* process.

No guidance or support is provided with said method practiced in a human subject with the desired effects. The state of the prior art provides evidence for the high degree of unpredictability as stated above. Thus, the specification lacks adequate guidance/direction to enable a skilled artisan to practice the claimed invention commensurate in scope with the claims.

In addition, no working examples are provided to rectify the missing information in the instant specification pertaining to the claimed gene therapy or gene transfer methods. The nature and properties of the claimed invention is difficult to ascertain absent empirical evidence. Thus, the specification does not provide support for the broad scope of the claims which encompass a

human and any organism to undergo the recited method involving expressing ferritin in a patient. The specification lacks adequate guidance/direction to enable a skilled artisan to practice the claimed invention commensurate in scope with the claims.

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

Response to Arguments

6. Applicant's remarks have been considered in full. Note that the rejections of record are withdrawn, thus applicant's comments are moot and will not be addressed herein. Note however, that new grounds of rejections have been instituted under 35 USC 112, first paragraph for the reasons set forth above.

Conclusion

7. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652